

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

- 1 1. (Currently amended): A computer-implemented method for managing
2 stability studies, the method comprising:

3 forwarding, to a first client computer, information configured to display[[ing.]] on
4 at least one display device; a first interface in a first set of one or more first graphical user
5 interfaces that enables [[a]] users of the first client computer to create stability studies by
6 specifying requirements that need to be fulfilled for the stability studies;

7 receiving, at a first host computer, first input specified by a user of the first client
8 computer via the first interface in the first set of one or more first graphical user interfaces, the
9 first input indicative of a set of requirements for at least one first stability study;

10 forwarding, to the first client computer, information configured to display[[ing.]]
11 on the at least one display device; a second interface in the first set of one or more second
12 graphical user interfaces that enables [[a]] the users of the first client computer to create
13 workflows associated with stages of stability studies, a workflow including information
14 configured to prompt a workflow participant user to perform one or more actions that need to be
15 taken during a stage associated with a stability study in order to fulfill requirements specified for
16 the stability study;

17 receiving, at the first host computer, input specified by the user of the first client
18 computer via the second interface in the first set of one or more second graphical user interfaces,
19 the second input indicative of a set of workflows associated with a plurality of stages of the at
20 least one first stability study, each workflow in the set of workflows specifying a set of actions
21 that need to be taken during each stage in the plurality of stages of the at least one first stability
22 study;

23 forwarding, to the first client computer, information configured to display[[ing,]]
24 on the at least one display device; a third interface in the first set of one or more third graphical
25 user interfaces that enable [[a]] the users of the first client computer to specify business rules for
26 the stability studies;

27 receiving, at the first host computer, third input specified by the user via the third
28 interface in the first set of one or more third graphical user interfaces, the third input indicative of
29 a set of business rules for the at least one first stability study;

30 generating, at a data processing device, a second set of one or more fourth
31 graphical user interfaces for the at least one first stability study with a data processing device
32 based on the set of requirements that need to be fulfilled for the at least one first stability study,
33 the set of workflows associated with the plurality of stages of the at least one first stability study,
34 and the set of business rules for the at least one stability study, wherein the second set of one or
35 more fourth graphical user interfaces define the set of requirements for the at least one stability
36 study;

37 forwarding, to a second client computer, information configured to display[[ing,]]
38 on the at least one display device, the one or more fourth interfaces in the second set of graphical
39 user interfaces;

40 receiving, a second host computer, input information specified by one or more
41 users of the second client computer via the one or more fourth interfaces in the second set of
42 interfaces, the received input information for fulfilling the requirements of the at least one
43 stability study; and

44 validating, by the second host computer, the received input information using the
45 data processing device against the set of business rules for the at least one stability study to
46 determine whether the input information is acceptable.

1 2. (Currently amended): The method of claim 1, further comprising if the
2 input information specified by the one or more users of the second client computer is acceptable,
3 storing the input information specified by the one or more users of the second client computer
4 using a storage device.

1 3. (Currently amended): The method of claim 1, further comprising:
2 determining, by the data processing device, whether the set of requirements for
3 the at least one first stability study have been completed; and
4 if the set of requirements have not been completed, outputting, on the at least one
5 display device, one or more fifth interfaces requesting, using the data processing device,
6 additional input information for the requirements in the set of requirements that have not been
7 completed.

1 4. (Currently amended): The method of claim 1, further comprising:
2 determining, by the data processing device, whether approval from a user is
3 needed for the input information specified by the one or more users of the second client
4 computer based on the set of workflows associated with the plurality of stages of the at least one
5 stability study.

1 5. (Currently amended): The method of claim 4, further comprising:
2 receiving, at the data processing device, an indication of approval for the
3 information specified by the one or more users of the second client computer from the user; and
4 storing the indication using a storage device.

1 6. (Original): The method of claim 5, wherein the indication comprises at
2 least one of an electronic signature and captured signature.

1 7. (Currently amended): The method of claim 4, further comprising:
2 receiving, at the data processing device, an indication from the user of disapproval
3 for the information specified by the one or more users of the second client computer;
4 determining, by the data processing device, requirements that need to be
5 completed for approval; and
6 requesting, using the data processing device, outputting, on the at least one
7 display device, one or more fifth interfaces defining that the determined requirements that need
8 to be completed for approval.

1 8. (Currently amended): The method of claim 1, wherein the first set of one
2 or more second graphical user interfaces include an interface for a stage in the plurality of stages
3 in the at least one first stability study.

1 9. (Original): The method of claim 8, wherein the plurality of stages
2 comprise at least two of a stability study setup criteria, stability study planning criteria, initial
3 sampling and testing criteria, stability study launch criteria, stability study testing criteria, and
4 stability study evaluation criteria.

1 10. (Currently amended): The method of claim 1, further comprising
2 outputting, from the data processing devic, on the at least one display device, information
3 summarizing the at least one first stability study.

1 11. (Currently amended): The method of claim 1, further comprising
2 determining, by the data processing device, a result of the at least one first stability study.

1 12. (Currently amended): The method of claim 11, wherein determining, by
2 the data processing device, the result of the at least one stability study comprises receiving the
3 result from is inputted by a user.

13-26 (Canceled).

1 27. (Currently amended): A tangible computer readable medium storing a set
2 of instructions for managing a stability study when executed by a processor of a data processing
3 system, the computer readable medium comprising:

4 code for forwarding information configured to display[[ing]] a first interface in a
5 first set of one or more first graphical user interfaces that enable a user to create stability studies;
6 by specifying requirements that need to be fulfilled for the stability studies;

7 code for receiving first input via the first interface in the first set of one or more
8 first graphical user interfaces, the first input indicative of a set of requirements for at least one
9 first stability study;

10 code for forwarding information configured to display[[ing]] a second interface in
11 the first set of one or more second graphical user interfaces that enable a user to create
12 workflows associated with stages of stability studies, a workflow including information
13 configure to prompt a workflow participant user to perform one or more actions that need to be
14 taken during a stage associated with a stability study in order to fulfill requirements specified for
15 the stability study;

16 code for receiving second input via the second interface in the first set of one or
17 more second graphical user interfaces, the second input indicative of a set of workflows
18 associated with a plurality of stages of the at least one first stability study, each workflow in the
19 set of workflows specifying a set of actions that need to be taken during for each stage in the
20 plurality of stages of the at least one first stability study;

21 code for forwarding information configured to display[[ing]] a third interface in
22 the first set of one or more third graphical user interfaces that enable a user to specify a set of
23 business rules for stability studies;

24 code for receiving third input via the third interface in the first set of one or more
25 third graphical user interfaces, the third input indicative of a set of business rules for the at least
26 one stability study;

27 code for generating a second set of one or more fourth graphical user interfaces
28 for the at least one first stability study based on the set of requirements that need to be fulfilled
29 for the at least one first stability study, the set of workflows associated with the plurality of
30 stages of the at least one first stability study, and the set of business rules for the at least one
31 stability study, wherein the second set of one or more fourth interfaces define the set of
32 requirements for the at least one stability study;

33 code for forwarding information configured to display[[ing]] [[the]] one or more
34 fourth interfaces in the second set of graphical user interfaces;

35 code for receiving fourth input information via the one or more fourth interfaces
36 in the second set of graphical user interfaces, the received fourth input information for fulfilling
37 the requirements of the at least one stability study; and

38 code for validating the received fourth input information against the set of
39 business rules for the at least one stability study to determine whether the fourth input
40 information is acceptable.

1 28. (Currently amended): The computer readable medium of claim 27, further
2 comprising code for storing the fourth input information when the fourth input information is
3 acceptable.

1 29. (Currently amended): The computer readable medium of claim 27, further
2 comprising:
3 code for determining whether the set of requirements for the at least one first
4 stability study have been completed; and
5 code for ~~outputting one or more fifth interfaces when the set of requirements have~~
6 ~~not been completed that requesting~~ additional input information for the requirements in the set of
7 requirements that have not been completed.

1 30. (Currently amended): The computer readable medium of claim 27, further
2 comprising:
3 code for determining whether approval from a user is needed for the fourth input
4 information based on the set of workflows associated with the plurality of stages of the at least
5 one stability study.

1 31. (Currently amended): The computer readable medium of claim 30, further
2 comprising:
3 code for receiving an indication of approval for the fourth input from the user; and
4 code for storing the indication.

1 32. (Previously presented): The computer readable medium of claim 31,
2 wherein the indication comprises at least one of an electronic signature and captured signature.

1 33. (Currently amended): The computer readable medium of claim 30, further
2 comprising:
3 code for receiving an indication ~~from the user~~ of disapproval for the fourth input;
4 code for determining requirements that need to be completed for approval; and
5 code for requesting that outputting one or more fifth interfaces defining the
6 determined requirements ~~that need to~~ to be completed for approval.

1 34. (Currently amended): A system for managing stability studies, the system
2 comprising:
3 a set of one or more processors; and
4 one or more memories coupled to the set of processor, the one or more memories
5 including:
6 a first set of one or more graphical user interfaces configured to enable a
7 user to create stability studies by specifying requirements that need to be fulfilled for stability
8 studies, workflows associated with stages of stability studies, and business rules for stability
9 studies;
10 a database configured to store information associated with the
11 requirements, the workflows, and the business rules for stability studies, wherein a workflow
12 includes information configured to prompt a user to perform one or more actions that need to be
13 taken during a stage associated with a stability study in order to fulfill requirements specified for
14 the stability study;
15 a stage selector configured to select a stage of a stability study ~~and to~~
16 determine ~~from the database one or more requirements for the selected stage;~~
17 a stage information manager configured to receive ~~from the database one~~ one
18 or more requirements ~~that need to be fulfilled for the selected stage and one or more workflows~~
19 ~~associated with the selected stage from the stage selector,~~ to generate a second set of one or more
20 graphical user interfaces that defines the one or more requirements for the selected stage that
21 need to be fulfilled[[,]] and ~~to generate a third interface indicative of information on~~ actions
22 associated with the selected stage that need to be performed;

23 a stage information processor configured to receive input specified via the
24 second ~~and third~~ set of graphical user interfaces and to validate the input against business rules
25 associated with the selected stage to determine whether the input is acceptable.

1 35. (Currently amended): The system of claim 34 wherein the first set of one
2 or more graphical user interfaces is further configured to enable the user to create a specification
3 for a first stability study as an overlay using a specification for a second stability study as a base.